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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/607,716

06/27/2003

Roger D. Tung

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EXAMINER

TUCKER, ZACHARY C

ART UNIT

PAPER NUMBER

1624

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

02/27/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/607,716	Applicant(s) TUNG ET AL.	
	Examiner Zachary C. Tucker	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 9-31 and 33-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 32 and 43 is/are rejected.
- 7) ☒ Claim(s) 2-8 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1624

DETAILED ACTION

Requirement for Restriction

~and~

Election of Species

On 9th August 2006, a written Requirement for Restriction, with a further requirement for applicant to elect a single disclosed species of whichever invention was elected, was mailed to applicants' counsel.

In reply to the Requirement, filed 11 December 2006, applicants indicated election of the invention of Group I, claims 1-32 and 43, which is drawn to chemical compounds of the formula (I), without traverse. The single disclosed species of the elected invention chosen by applicants was 149, found in Table 6, on page 99 of the substitute specification. The elected species compound is embraced by the instant claims where W is $-C(O)-R^2$ with R^2 being hydrogen; L is ethyl; A^1 is the pyrrolidine containing moiety set forth in claim 1, with R^5 and R^6 being hydrogen, X being $-O-$, Y being $-CH_2-$, and Z being phenyl; V is $-NH-$; K is $-C(O)-$; and T is phenyl.

Claims of Group II (33-42) now stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention. At such time that the elected Group is in allowable form, claims of Group II will be eligible for rejoinder and the Requirement for Restriction between Groups I and II will be withdrawn.

A search of Group I claims' subject matter was begun, wherein the compounds searched were comprised of the pyrrolidine-containing moiety alternative of A^1 , and no prior art rendering such compounds unpatentable was found. At that time, the search was broadened, in accordance with "Markush practice" which is explained in MPEP 803.02. Prior art anticipating some subject matter embraced by Group I claims was found, whereupon the search was stopped. Thus, claims 9-31, which do not read on the elected

Art Unit: 1624

species, or on *any* compound according to instant claim 1 wherein K is a carbonyl group – C(O)–, are withdrawn from consideration.

Claims 1-8, 32 and 43, although not withdrawn, have not been fully searched, due to the nature of examination when an election of species requirement is operative, as is the case with the instant application. Those compounds wherein K is –S(O)₂–, or K, V, A¹ and A² are all bonds, or all of the various combinations of *some of* K, V, A¹ and A² being bonds and *some of* K, V, A¹ and A² being present have not been searched.

Indication of allowable subject matter, and claim rejections based on prior art, are found on the following pages.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thornton*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8, 32 and 43 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-26 of U.S. Patent No. 6,265,380.

The patent issued from application serial number 09/293-247, which is one of the parent

Art Unit: 1624

applications to the instant application. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds according formula (II) as specified in the claims of the patent are, as defined by the specification of that patent, inclusive of species embraced by the instant claims. In claim 1 of the patent, A¹ is limited only to the pyrrolidine-containing group specified in the instant claims, and A² is limited only to the acyclic moiety as specified in the instant claims.

For example, Table 1 in the patent, which serves to more specifically define formula (II) compounds as claimed therein, describes a series of compounds embraced by formula (I) according to the instant claims wherein: T is pyrazinyl; K is -C(O)-; V is -NH-; A² is the nitrogen and carbonyl-containing moiety; A¹ is the pyrrolidine ring-containing moiety; L is ethyl and W is a formyl group -C(O)H. At least one compound in Table 1 of the patent has a phenyl ring at the "Z" position, substituted with a "J" group, which renders compounds of instant claim 43 obvious. Compounds 9 and 11 in Table 1 have such a configuration - the "J" substituent in compound 9 is trifluoromethoxy (alkoxy - methoxy - substituted with three J¹ groups - halo - fluorine), and the "J" substituent in compound 11 is "aryl" (phenyl) and is. Instant claims 7 and 8, it is noted, are not embrative of compounds described in Table 1 of the patent, but claims 6-8 of the patent specify substituent groups on "L," just as instant claims 7 and 8 do.

Claims 1 and 43 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6,617,309, which issued from application serial number 09/875,390, one of the parent applications to the instant application. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds according formula (II) as

Art Unit: 1624

specified in the claims of the patent are, as defined by the specification of that patent, inclusive of species embraced by the instant claims. In claim 1 of the patent, both A¹ and A² are limited only to the acyclic moieties as are specified in the instant claims.

For example, Table 4 in the patent describes which serves to more specifically define formula (II) compounds as claimed therein, describes a series of compounds embraced by formula (I) according to the instant claims wherein T is aryl or heteroaryl; K is -C(O)-; V is -NH-; A¹ and A² both are the acyclic moieties specified in the instant claims; L is ethyl; and W is a formyl group, -C(O)H. Because claim 1 of the patent includes a proviso that excludes compounds wherein T is aryl when T is R¹² (as is the case with the compounds identified from Table 4), only those compounds of claim 1 (of the patent) wherein T is heteroaryl are considered to render compounds according to the instant claims obvious. In Table 4, these compounds at least include those numbered 89, 91-95, 98 and 100. Instant claim 43 is rendered obvious by the claims of the patent, because the "Z" group, which is limited to phenyl in that claim, is an optional limitation in instant claim 1.

According to chapter 804 of the MPEP, wherein double patenting is explained, a patent specification, although not available as prior art - such as reliance on the specification for motivation in an obviousness analysis, may be referred to in making a double patenting rejection if it is used as "dictionary" to learn the meaning of a term recited in the claims [*Toro Co. v. White Consol. Indus., Inc.*, 199 F.3d 1295, 1299, 53 USPQ 2d 1065, 1067 (Fed. Cir. 1999)], and those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent [*In re Vogel*, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA

Art Unit: 1624

1970)]. The specifications of both of the patents cited hereinabove were relied upon only in the manner prescribed by the *Toro v. White Consol. Indus., Inc.* and *In re Vogel* decisions.

Claim Rejections - 35 USC § 102

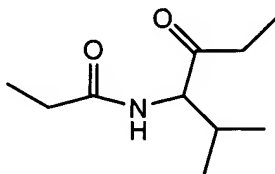
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 32 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Lehmann et al, "Über die chemischen und biologischen Eigenschaften einiger α -Aminoketone" Helvetica Chimica Acta, vol. 33, pages 1217-1226 (1950).

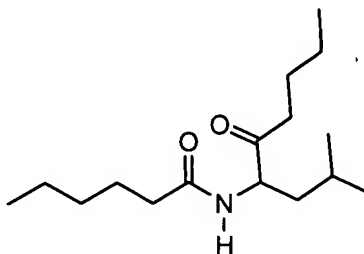
The Lehmann et al article describes aminoketone compounds. Some of the intermediates synthesized by Lehmann et al in producing the aminoketones are carboxamide compounds within the scope of instant claim 1. On page 1221, synthesis of "DL-4-propionylamino-6-methyl-heptanone-(3)," which would be named DL-4-propionylamino-6-methyl-heptan-3-one according to the nomenclature system most widely used today, is described. The compound has a structure represented by the following diagram:



and is embraced by instant claims 1, 32 and 43 wherein T is R¹² and R¹² is hydrogen; M is alkyl (pentyl); L alkyl (isobutyl); W is -C(O)-R², and R² is alkyl (pentyl). All of A¹, A², V and K are bonds.

Art Unit: 1624

On page 1222, synthesis of "DL-9-methyl-7-caproylamino-decanon-(9)" is described, which would be named which would be named DL-9-methyl-7-caproylamino-decan-9-one according to the nomenclature system most widely used today, is described. The compound has a structure represented by the following diagram:



and is embraced by instant claims 1, 32 and 43 wherein T is R¹² and R¹² is hydrogen; M is alkyl (ethyl); L alkyl (is isobutyl); W is -C(O)-R², and R² is alkyl (ethyl). All of A¹, A², V and K are bonds.

Instant claim 43 is anticipated by the Lehmann et al reference because it further limits an optional element of claim 1, the "Z" group. Lehmann et al discloses compounds wherein A¹ is a bond, so "Z" is absent in those compounds.

Allowable Subject Matter
~and~
Comments

Claims 2-8 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims, and to limit the variable "K" to -C(O)- only. The formula (I) compounds wherein "K" is -S(O)₂- have not been searched, because prior art wherein "K" is -C(O)-, as it is in the elected species, was discovered which prompted termination of the search. As stated in the section hereinabove headed "Requirement for Restriction and Election of Species," claims 32 and 43 have been searched only insofar as they embrace the elected species compound, or subject matter as specified in any of the

Art Unit: 1624

other claims which is indicated in this Office action as being allowable. Compounds according to the instant claims wherein K is a sulfonyl group $-S(O)_2-$ have not been searched.

As close prior art with respect to the present invention, the examiner would of course point up the references cited in applicants' Information Disclosure Statement, and the Lehmann et al article cited in the rejection of claim 1. Also of interest however is US 5,502,061 (Hui et al), which describes HIV protease inhibitors resembling those compounds of formula (I) wherein A¹ is the acyclic moiety. Hui et al's compounds lack a group corresponding in structure to "W" as specified in instant claim 1, however (see col. 7, molecular structure diagram).

The compounds of the present invention include at least two carboxamide groups, and therefore are broadly similar to most protease inhibitor drugs known from the prior art. The specific combination of variables in formula (I), especially the different identities for "W," is not disclosed or suggested in the prior art.

In order to prevent any patentability issues from arising upon rejoinder of Group II claims (such as rejection of Group II claims under 35 U.S.C. 112, first paragraph, for lack of enablement), the examiner recommends limiting the method claims in Group II to only the *treatment* of hepatitis C virus infection. Inhibition of serine proteases, generally, and prevention of hepatitis C virus infection do not find enabling support in the instant specification.

Rejoinder of the pharmaceutical composition claims in Group II will not be problematic.

Conclusion

Any inquiry concerning this communication should be directed to Zachary Tucker whose telephone number is (571) 272-0677. The examiner can normally be reached

Art Unit: 1624

Monday to Friday from 5:45am to 2:15pm. If Attempts to reach the examiner are unsuccessful, contact the examiner's supervisor, James O. Wilson, at (571) 272-0661.

The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

A handwritten signature in black ink, appearing to read 'ZC Tucker', written over a horizontal line.

ZACHARY C. TUCKER
PRIMARY EXAMINER